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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,315	03/03/2004	Robert C. O'Brien	31611.0031	4362

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EXAMINER	
HELLER, TAMMIE K	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,315	O'BRIEN, ROBERT C.	
	Examiner	Art Unit	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11302005* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Non-patent literature*.

DETAILED ACTION

1. The amendments filed on October 20, 2005, November 10, 2005 and November 18, 2005 have been received and considered. By these amendments, claim 14 has been cancelled; claims 1, 4, 5, 11, 13 and 15 have been amended and claims 1-13, 15 and 16 are now pending in the application.

Double Patenting

2. In view of the applicant's amendment to the claims and the present state of co-pending application number 10/719,632, Examiner is withdrawing the double patenting rejection which was made against claims 1-16 in the last Office action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-8, 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeHaan et al. (U.S. Patent No. 4,542,752) in view of Mohanty et al. (Biomol Eng. 2002 Aug;19(2-6):125-8), Allen et al. (J Biomed Mater Res. 2001 May 1;58(3):319-28), and Cui et al. (Surface Coatings Technol 2000;131:481-487).

5. Regarding claim 1, DeHaan et al. discloses implantable electrodes which include a substrate 31, a biocompatible and electrically conductive intermediate

coating 32 supported on the substrate and a carbon-containing coating 27a adhered to the intermediate coating (see Figure 3 and col. 3, ln. 51-67). However, DeHaan et al. does not disclose the structural nature of carbon-containing coating 27a. Mohanty, Allen, and Cui discuss laboratory experiments performed in order to assess the biocompatibility of amorphous diamond-like carbon (DLC) coatings on conductive substrates. Furthermore, Cui discusses the biocompatibility of amorphous carbon nitride coatings on conductive surfaces. Each of these studies concluded that amorphous DLC, and amorphous carbon nitride in the Cui article, comprise extremely biocompatible coatings for implantable medical devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize an amorphous DLC coating, as taught by Mohanty, Allen, and Cui, or an amorphous carbon nitride coating, as taught by Cui, as the carbon-containing coating on the implantable electrode of DeHaan et al. in order to ensure optimal biocompatibility of the implantable electrodes.

6. Regarding claim 2, DeHaan et al. discloses that the substrate 31 may be a metal such as tantalum, titanium, iridium, platinum or niobium (see col. 3, ln. 55-62).

7. Regarding claim 3, DeHaan et al. discloses that the substrate may be an alloy of any of the metals including tantalum, titanium, iridium, platinum and niobium, therefore the substrate of DeHaan et al. may be platinum/iridium (see col. 3, ln. 60-62).

8. Regarding claim 4, DeHaan et al. discloses that intermediate coating 32 may be titanium (see col. 3, ln. 63-65).

9. Regarding claim 5, the carbon-containing coating disclosed by Cui is disclosed to be amorphous carbon nitride.

10. Regarding claim 6, Cui discloses on page 483, column 1, lines 3-8, that the carbon nitride film was enhanced when nitrogen is provided in the carbon-containing coating at a concentration of approximately 9 atomic percent, which falls within the range of 1 ppm to about 57 atomic percent.

11. Regarding claim 7, the DLC coating of Mohanty is disclosed to be deposited by the plasma enhanced chemical vapor deposition (PECVD) technique (see page 125, col. 1, ln. 11-12).

12. Regarding claim 8, DeHaan et al. discloses a process for making the implantable electrode which includes providing an electrically conductive substrate member which is porous (see col. 8, ln. 62-65). DeHaan et al. further discloses that the substrate member is made porous by sinter processing (see col. 9, ln. 22-23).

13. Regarding claim 10, Mohanty discloses that the carbon-containing coating has a thickness of between 1 and 5 microns (see page 125, col. 2, ln. 18-19). Therefore, the coating of Mohanty falls within the 10 nm to 1.0 μm thickness range. Furthermore, Allen discloses in Table I on page 320 that using fast atom bombardment, the DLC film thickness that is achieved is 0.50 μm.

14. Regarding claim 11, DeHaan et al. discloses implantable electrodes which include a substrate 31 which may be an alloy of any of the metals including

tantalum, titanium, iridium, platinum and niobium (see col. 3, ln. 60-62), a biocompatible and electrically conductive intermediate coating 32 supported on the substrate which may be a titanium alloy (see col. 3, ln. 63-65), and a carbon-containing coating 27a adhered to the intermediate coating (see Figure 3 and col. 3, ln. 51-67). However, DeHaan et al. does not disclose the structural nature of carbon-containing coating 27a. Mohanty, Allen, and Cui discuss laboratory experiments performed in order to assess the biocompatibility of amorphous diamond-like carbon (DLC) coatings on conductive substrates. Furthermore, Cui discusses the biocompatibility of amorphous carbon nitride coatings on conductive surfaces. Each of these studies concluded that amorphous DLC, and amorphous carbon nitride in the Cui article, comprise extremely biocompatible coatings for implantable medical devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize an amorphous DLC coating, as taught by Mohanty, Allen, and Cui, or an amorphous carbon nitride coating, as taught by Cui, as the carbon-containing coating on the implantable electrode of DeHaan et al. in order to ensure optimal biocompatibility of the implantable electrodes.

15. Regarding claim 12, the carbon-containing coating disclosed by Cui is disclosed to be amorphous carbon nitride.

16. Regarding claim 13, DeHaan et al. discloses implantable electrodes which include a substrate 31 which may be an alloy of any of the metals including tantalum, titanium, iridium, platinum and niobium (see col. 3, ln. 60-62), a biocompatible and electrically conductive intermediate coating 32 supported on

the substrate which may titanium (see col. 3, ln. 63-65), and a carbon-containing coating 27a adhered to the intermediate coating (see Figure 3 and col. 3, ln. 51-67). However, DeHaan et al. does not disclose the structural nature of carbon-containing coating 27a. Mohanty, Allen, and Cui discuss laboratory experiments performed in order to assess the biocompatibility of amorphous diamond-like carbon (DLC) coatings on conductive substrates. Furthermore, Cui discusses the biocompatibility of amorphous carbon nitride coatings on conductive surfaces. Each of these studies concluded that amorphous DLC, and amorphous carbon nitride in the Cui article, comprise extremely biocompatible coatings for implantable medical devices. Furthermore, Cui discloses on page 482, col. 1, paragraph 4, lines 4-5 that the DLC coating may be deposited via a sputtering technique. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize an amorphous DLC coating, as taught by Mohanty, Allen, and Cui, or an amorphous carbon nitride coating, as taught by Cui, as the carbon-containing coating on the implantable electrode of DeHaan et al. in order to ensure optimal biocompatibility of the implantable electrodes.

17. Regarding claim 15, the carbon-containing coating disclosed by Cui is disclosed to be amorphous carbon nitride.

18. Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeHaan et al. in view of Mohanty, Allen, and Cui as applied to claims 1-8, 10-13 and 15 above, and further in view of Frericks et al. (U.S.

2004/0127966, cited in prior office action). DeHaan et al. in view of Mohanty, Allen, and Cui discloses the invention essentially as claimed, but remains silent as to the required thickness for the intermediate coating. Frericks et al. discloses a stimulation electrode with an intermediate coating layer, which has a thickness of 1 nm to 20 μm (see paragraph 18). Frericks teaches that the prescribed thickness for the intermediate coating layer is optimally chosen such that it offers sufficient oxidation protection while not substantially affecting the surface structure of the substrate. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of DeHaan et al. in view of Mohanty, Allen, and Cui with those of Frericks et al. It would have been obvious to modify the intermediate coating on the electrodes of DeHaan et al. to have the thickness prescribed by Frericks in order to provide the electrode with sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

Response to Arguments

19. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

TKH